

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND  
*Southern Division***

Hospira, Inc.

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Plaintiff,

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v.

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Sylvia Mathews Burwell, et al.

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Case No. GJH-14-02662

Defendants.

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**PLAINTIFF HOSPIRA’S OPPOSITION TO INTERVENOR-DEFENDANT PAR  
STERILE PRODUCT, LLC’S RE-FILED MOTION FOR A SECURITY BOND**

Plaintiff Hospira, Inc. (“Hospira”) submits this memorandum in opposition to the Motion for a Security Bond (“Motion for Bond”), which was originally filed under seal by Intervenor-Defendant Par Sterile Products, LLC (“Par”) (ECF No. 88), stricken for failure to comply with Court rules for filing papers under seal (ECF No. 103), and re-filed by Par on September 3, 2014. (ECF No. 111). Hospira incorporates by reference the arguments it set forth in its earlier-filed protective opposition. (ECF No. 99).

The Motion for Bond should be denied for the following reasons:

Par fails to provide any good reason why a bond should be required in this case. Virtually all of its claimed injuries are predicated on the preposterous notion that the Court’s TRO, or some other form of preliminary injunctive relief, will be in place until June 2015. Far from supporting the need for a bond, the information submitted to the Court in support of Par’s motion confirms that the circumstances of this case fully justify waiving a bond requirement. Waiving the Rule 65(c) requirement for a bond is entirely within the court’s discretion and is the right thing to do in this case. *Pashby v. Delia*, 709 F.3d 307, 331-32 (4th Cir. 2013) (The district

court “retains discretion to set the bond amount as it sees fit or to waive the security requirement” altogether); *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 421-22 & n.3 (4th Cir. 1999) (citing *Int’l Controls Corp. v. Vesco*, 490 F.2d 1334 (2d Cir. 1974), in which the appellate court approved the district court’s fixing bond amount at zero in the absence of evidence regarding likelihood of harm); *see also Potomac Conf. Corp. v. Takoma Acad. Alumni Ass’n*, No. DKC-12-1128, 2014 U.S. Dist. LEXIS 27123 (D. Md. Mar. 4, 2014) (“The district court has discretion in fixing the amount for the security bond, and in circumstances where the risk of harm is remote, a nominal bond may suffice.”). The Motion for Bond should be denied.<sup>1</sup>

It is undisputed that Par took full advantage of the 36-hour delay between the FDA’s contested docket decision and the Court’s TRO to fill the warehouses and shelves of its customers with a six-week supply of generic Precedex. What is now revealed in the Motion for Bond is that Par’s feverish efforts during that 36 hours to get its product out of its own warehouses, and therefore beyond the reach of the Court’s TRO, have been handsomely rewarded with huge profits--\$[see amount disclosed in Par’s papers] in clear profit by Par’s own reckoning. *See* Supp. Decl. of Tony Pera (ECF No. 88-2) (“Pera Supp.”) at ¶ 4 (disclosing net sales and cost of goods sold); *see also* Supp. Decl. of John C. Staines, Jr. (ECF No. 88-1) (“Staines Supp.”) at ¶ 3 (calculating profit on sales of the generic Precedex that Par shipped to its customers before the TRO was entered).

Par further admits that its distribution pipeline is now so clogged with surplus generic Precedex that its customers will not need to re-order until mid-September at the earliest. Pera Supp. at ¶ 6; Staines Supp. at ¶ 4. By then, given the Court’s accelerated schedule, the expectation of all parties--with the possible exception of Par--is that a final judgment on the cross-motions for summary judgment will have been entered. Even if there is no final judgment,

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<sup>1</sup> If the Court nevertheless determines that a bond should be posted, it should be in a nominal amount.

the TRO will expire no later than September 16, or mid-September, before Par has incurred any measurable harm.

As Hospira previously argued, because the FDA has been temporarily stayed from granting further approvals of ANDAs for generic Precedex, and because Mylan is the only other company with an approved ANDA and is constrained by the same TRO that constrains Par, Par has lost no market momentum or advantageous market position relative to other generic competitors by reason of the TRO. To the contrary, the TRO is working to keep other section viii filers off the market, thus preserving and solidifying Par's market position until either the TRO is lifted or final judgment on the merits is entered.

Par tries to muster some colorable claim of injury resulting from the TRO, but its efforts fall far short of the mark. It claims that besides its five "existing" customers (those with the fully-stocked warehouses and storage shelves that Par was able to supply pre-TRO), "five additional customers have approached Par" to purchase its generic Precedex. Pera Supp. at ¶ 3. Mr. Pera seems to imply--though, notably, never actually says--that Par turned these customers away on account of the TRO. Giving Par the benefit of the doubt on that point, the information about these lost transactions is still suspiciously thin, and certainly not any basis on which the Court could properly determine that a security bond is necessary, let alone what the amount of such a bond should be. Par's motion papers disclose nothing about the size of these customers, what quantity of generic Precedex they were interested in buying, what price they were willing to pay and whether Par would have been willing to sell to them at that price, when they wanted delivery, and so on. Par cannot reasonably expect the Court to fill in all these information gaps, but that is apparently what Par is hoping the Court will do. If Par truly had a legitimate need for a bond--which co-defendant Mylan, in the same shoes, saw fit to waive--then it should be able to

do better than ask the Court to engage in rank speculation about the need for and appropriate size of a bond.

Par also conjures a “loss” on account of an expiring shelf-life of inventory it has on hand, with a supposed “net sales” value of \$[**see amount in Par’s papers**]. Pera Supp. at ¶ 7 (ECF No. 111-2). Apart from the significant facts that (a) Par’s bad decision to gamble on the supposed certainty and timing of its entry into the market by stockpiling large inventories of generic Precedex a full year ago cannot be blamed on Hospira or the TRO, and that (b) by its own admission, this inventory remains salable long after the TRO will have expired, *see id.* (“products will not be salable after November 2014”), Par is just playing games with the numbers. If the inventory becomes unsalable because of a looming expiration date, then the relevant number for purposes of estimating loss is, at most, cost of goods, not net sales. As Par’s submission plainly illustrates, its cost of goods for generic Precedex is a tiny fraction--less than [**see percentage in Par’s papers**]--of its “net sales price,” *see* Pera Supp. at ¶ 4 (ECF No. 111-2); Staines Supp. at ¶ 3 (ECF No. 111-1), which may explain why Par considered its stockpiling strategy an acceptable risk.

There is no better indication of Par’s over-reaching and lack of credibility than the gargantuan size of the bond it has requested--\$34,164,352 (give or take, presumably)--virtually all of which is predicated on the highly dubious notion that a TRO or some version of a preliminary injunction will continue for months and months. At the hearing on August 26, Par suggested a \$26 million bond in anticipation of a potential 10-month delay in getting to a final judgment (ECF No. 77, tr. at 112-13). The Court could not have been plainer in its forecast that the relevant period was a matter of days, not months. *Id.* Notwithstanding this guidance from the Court, Par’s proposed bond amount, grossly over-reaching as it was, has only gotten larger.

Given the accelerated schedule, Par would have done well to follow Mylan's lead and waive the bond. It has failed to demonstrate why a bond is needed, or if needed, demonstrate in any sensible way how much it should be, which is its burden. *Potomac Conf. Corp.*, 2014 U.S. Dist. LEXIS 27123, at \*73-75 (setting a nominal bond in light of the defendant's failure to provide any meaningful evidence to assess the amount of the bond). To the contrary, its own admissions demonstrate that there is no genuine risk of lost sales, or any other kind of cognizable loss, until after the TRO has been dissolved. There is no credible, non-speculative basis on which to conclude that there will be any losses for the short period of time that the TRO is in place. Accordingly, Hospira respectfully requests that the Court, in the exercise of its sound discretion, waive the bond requirement or impose, at most, a bond in a nominal amount.

Respectfully submitted,

Dated: September 4, 2014

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 4th day of September, 2014, a copy of the foregoing PLAINTIFF HOSPIRA'S OPPOSITION TO INTERVENOR-DEFENDANT PAR STERILE PRODUCT, LLC'S RE-FILED MOTION FOR A SECURITY BOND is available for viewing from the Court's ECF system. Notice of this filing will be sent to all counsel of record via the Court's ECF system.

/s/ Ralph S. Tyler  
Ralph S. Tyler